

Attorney Docket: 083022-0272515
Client Reference:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: MITCHELL E. EGGERS

Application No.: 10/007,355

Group No.: 1743

Filed: November 7, 2001

Examiner: ALEXANDER, Lyle

Title: SAMPLE CARRIER

**Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF (37 C.F.R. §41.37)

This brief is in furtherance of the Notice of Appeal, filed in this case on March 8, 2006. The time period for filing an appeal brief has been reset to May 13, 2006 by Notice of Panel Decision from Pre-Appeal Brief Review mailed April 13, 2003. This brief is being filed with a Petition for Extension of Time covering the time from May 13, 2006 until present.

The fees required under Section 1.17(c), and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL.

I. REAL PARTIES IN INTEREST

The real party in interest in this appeal is the following party:
GenVault Corporation.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal: None.

III. STATUS OF CLAIMS

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are: **52**

B. STATUS OF ALL THE CLAIMS IN APPLICATION

1. Claims canceled: **None**
2. Claims withdrawn from consideration but not canceled: **None**
3. Claims pending: **1-40, 58-69**
4. Claims allowed: **None**
5. Claims rejected: **1-40, 58-69**

C. CLAIMS ON APPEAL

The claims on appeal are: 1-40 and 58-69.

IV. STATUS OF AMENDMENTS

No amendments to the claims were submitted or made in the Application after the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Aspects of the present invention relate generally to a system and method of archiving and retrieving biological or non-biological samples maintained in desiccated form at a plurality of non-cross-contaminating discrete sample nodes on a carrier. Each "node" is a unitary structural element operative to maintain, carry, or otherwise to support a discrete sample as addressed, among other places, in the description of FIGS. 5A-5E beginning at page 31, line 24, and continuing to page 39, line 25, of the present application. A plurality of sample nodes is removably attached to a structural array at respective attachment points. Fig. 4A depicts an example of a sample carrier. Three independent claims are pending in the Application. For purposes of this Appeal, elements of the claims can be found at page 31, line 24, and continuing to page 39, line 25, of the present application and in Figs. 5A-5C.

Claim 1 is directed to a sample carrier comprising a structural array 520A and a plurality of discrete sample nodes 529. Each of the plurality of discrete sample nodes 529 is removably attached to the structural array 520A at a respective attachment point 523, 525. Each of the plurality of discrete sample nodes 529 comprises a sample support medium operative to carry a discrete sample in desiccated form.

Claim 20 is directed to a sample carrier comprising a plurality of structural arrays 520A (and see Fig 4A) supported in a predetermined spatial relationship and a plurality of discrete sample nodes 529. Each of the plurality of discrete sample nodes 529 is removably attached to one of the plurality of structural arrays 520A at a respective attachment point 523, 525. Each of the plurality of discrete sample nodes 529 comprises a sample support medium operative to carry a discrete sample in desiccated form.

Claim 58 is directed to a sample carrier comprising a structural array 520A comprising a plurality of discrete sample nodes 529 wherein each of the plurality of discrete sample nodes 529 comprises a discrete sample support medium operative to support sample material in desiccated form, and a specimen carried by the sample support medium in desiccated form at one or more of the plurality of discrete sample nodes 529. The plurality of discrete sample nodes 529 is removably attached to said structural array 520A at a respective attachment point 523, 525.

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

Claims 1, 20 and 58 have been rejected under 35 U.S.C. § 102(e) as being anticipated by PCT Patent Applications WO 01/31333 by Milosavijevic and WO 01/31317 by Hogan ("the '333 and '317 PCT applications"). Appellant respectfully submits that these rejections are in error, and seek review of the following issues:

- Whether the '333 and '317 PCT applications disclose attachment points at which a discrete sample node is removably attached to a structural array as required by independent claims 1 and 58.
- Whether the '333 and '317 PCT applications disclose attachment points at which a discrete sample node is removably attached to one of a plurality of structural arrays as required by independent claim 20.
- Whether the '333 and '317 PCT applications disclose a plurality of discrete sample nodes each discrete sample node being removably attached to a structural array at a respective attachment point and comprising a sample support medium operative to carry a discrete sample in a dessicated form as required by independent claims 1, 20 and 58.
- Whether the Examiner erred in disregarding a declaration by a coinventor of the '333 and '317 PCT applications that refutes the Examiner's finding that the '333 and '317 PCT applications disclose attachment points.

VII. ARGUMENTS

The § 102 rejection of claims 1, 20 and 58 based on the '333 and '317 PCT applications should be reversed. A cited prior art reference anticipates a claimed invention under 35 U.S.C. §102 only if every element of the claimed invention is identically shown in the single reference, arranged as they are in the claims. MPEP §2131; *In re Bond*, 910 F.2d 831, 832, 15 USPQ 2d 1566, 1567 (Fed. Cir. 1990). Each and every limitation of the claimed invention is significant and must be found in the single cited prior art reference. *In re Donohue*, 766 F.2d 531, 534, 226 USPQ 619, 621 (Fed. Cir. 1985).

As set forth more fully below, the '333 and '317 PCT applications do not disclose each and every element of the claims arranged as they are in the claims.

Independent Claims 1 and 58 Patentably Define Over The Prior Art

The prior art does not teach attachment points at which discrete sample nodes are removably attached.

Claims 1 and 58 require a plurality of discrete sample nodes being removably attached to a structural array at a respective attachment point. In the Office Action of December 8, 2005 ("the outstanding OA"), the Examiner cites the '333 and '317 PCT applications as teaching each and every element of the claims. Although, the references are silent regarding the attachment points recited in claims 1 and 58, the Examiner proposes that removing portions of a sample (from a sample card) can be read on the claimed "removably attached." See outstanding OA, page 4, first paragraph. Thus, the Examiner implicitly proposes attachment points that are necessarily located in a sample card.

However, in the first Office Action, the Examiner alleged that the claimed structural array is taught by a multi-well tray. See Office Action mailed September 13, 2004 at page 4, third paragraph; see also outstanding OA at page 4, first paragraph. Thus, the Examiner alleges that the sample card has attachment points and that the structural array is a separate multi-well tray. Accordingly, the act of creating alleged discrete sample nodes requires removing those alleged discrete sample nodes from their alleged attachment points before placing them in the multi-well tray (the alleged structural array).

Therefore, according to the Examiner's interpretation, the alleged plurality of sample nodes cannot be removably attached at respective attachment points as required in the claims. Therefore, Appellant submits that the cited art does not teach each and every element of the claims.

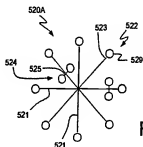


FIG. 5A



FIG. 5B

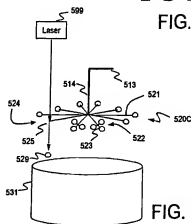


FIG. 5C

The Examiner also applied an improper interpretation of the term "discrete sample nodes." In the outstanding OA, the Examiner alleged that a node is any means to contain a sample; the Examiner also alleged that sample nodes are taught by "discrete samples placed into unique and discrete containers for subsequent analysis;" the Examiner further alleged that a punched-out sample "is a unified, distinct, individual sample and meets the instant claim." See the Outstanding Office Action, p4 at first paragraph and paragraph spanning pages 4 and 5. Appellant disagrees and asserts that the Examiner has improperly adopted an interpretation of "discrete sample node" that is both inconsistent with a fair reading of the claims and that is inconsistent with the ordinary usage of the term as it would be understood by one of ordinary skill in the art.

Sample nodes consistent with the claims are described and depicted in the Specification and Drawings as unitary structural elements attached to a structure in a structural array. Fig. 5B, as reproduced above, depicts five different examples of sample nodes and Figs 5A and 5C show the location of sample nodes 529 on an example of a structural array 520A, 520C. Figs. 5A, 5B and 5C and page 31, line 24 – page 32, line 11. It is apparent from the description and drawings that the each sample node is individually distinct from the other sample nodes. This arrangement and separation permits sample nodes to be arranged and configured as desired to, for example, be spatially positioned relative to a specimen or sample container. See, *also*, Fig 4A and page 28, lines 1-6.

Furthermore, the sample nodes required in claims 1 and 58 are discrete sample nodes. Appellant added the "discrete" qualification to "sample node" in the claims in an Amendment filed September 30, 2005 and in response to discussions in an August 22, 2005 interview with the Examiner. The qualification explicitly requires each of the plurality of sample nodes to be individually distinct from one another.

Nevertheless, the Examiner suggests that a sample punched from a sample card can be described as being removably attached and that samples are discrete provided the samples "are placed in areas of the card where they do not mix with other samples." See outstanding OA, paragraph spanning pages 4 and 5. However, as shown above, such interpretation does not provide discrete sample nodes removably attached to a structural array at respective attachment points. The Examiner finds discrete sample nodes after the punched samples are placed in micro-wells. This interpretation misconstrues the limitations as nodes for holding discrete samples when the prosecution history clearly shows that the term reflects sample nodes that are discrete. Nevertheless, Appellant submits that both the term "plurality of sample nodes" as originally provided in the claims and the term "plurality of discrete sample nodes" clearly require plural individually distinct sample nodes which are not taught by the prior art.

Furthermore, those skilled in the art would reach an interpretation of "discrete sample node" that would preclude a prior art rejection based on the '317 or '333 PCT applications. The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. MPEP 2111 citing *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999).

The word "node" is typically used to identify a point of origination, center or intersection. See Merriam-Webster Online at www.m-w.com. The word "discrete" is typically used in relation to separate entities, individually distinct or unconnected elements. *Id.* Thus a plurality of discrete sample nodes would be readily apprehended by one of skill in the art as indicating the existence of multiple nodes which are discrete from one another.

Finally, Appellant provides an example from the Specification that negates the Examiner's characterization of a prior art micro-well as a structural array. The description and drawings describe one embodiment of the claimed sample carrier 410 in which structural arrays 420A-420C are arranged in alignment with wells in *multi-well plate* 430. See Fig. 4A and page 28 at lines 24-30. Clearly, in the example, all of the required elements are provided with the use of the prior art micro-well tray cited by the Examiner as teaching a structural array. Such micro-well plate is provided external to the example embodiment.

Independent Claim 20 Patentably Defines Over The Prior Art

For the reasons provided above, the prior art does not disclose "attachment points" and "discrete sample nodes" also recited in claim 20. Additionally, The prior art does not teach a plurality of structural arrays arranged as required in claim 20 of the present Application. Claim 20 requires that each of a plurality of discrete sample nodes is removably attached to one of a plurality of structural arrays supported in a predetermined spatial relationship. As noted above, the Examiner alleged in prior Office Actions that the claimed structural array is taught by a multi-well tray and that portions of a sample removed by punching are "removably attached" to the sample. See Office Action mailed September 13, 2004 at page 4, third paragraph, and outstanding OA, page 4, first paragraph. Also as noted above, the prior art does not support such interpretation. Nor does the prior art teach a plurality of structural areas supported in a predetermined spatial relationship, even if sample cards or micro-well plates are alleged to be those structural arrays.

For at least the reasons provided, Appellant submits that the claims of the present Application patentably define over the art of record. Therefore Appellant requests withdrawal of the rejection of claims 1, 20 and 58. Appellant also requests withdrawal of

claims 2-19, 21-40 and 58-69 for at least the reason that these claims ultimately depend from allowable independent claims 1, 20 and 58.

The Examiner Erred In Disregarding Declaration Of An Inventor Of The Cited Prior Art

Examiner erred in disregarding properly submitted evidence traversing the claim rejections.

When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section. It is the responsibility of the primary examiner to personally review and decide whether affidavits or declarations submitted under 37 C.F.R. 1.132 for the purpose of traversing grounds of rejection are responsive to the rejection and present sufficient facts to overcome the rejection.

MPEP 716 citing 37 C.F.R. 1.132.

A co-inventor in the '333 and '317 PCT applications concurred that the cited art does not teach attachment points as recited in the claims in a declaration filed in the Application on September 30, 2005. In the declaration, Michael Hogan, a co-inventor of the cited '333 and '317 PCT applications, declared that following review of the specification and claims of the present application, he concluded that the "attachment points" recited in independent claims 1, 20 and 58 of the present Application are not described in the '317 or '333 PCT applications. In the outstanding Office Action, the Examiner dismissed Mr. Hogan's declaration as opinion because "[i]t is not clear how Mr. Hogan has read/understood/interpreted the claimed 'attachment points'." This dismissal does not acknowledge that Mr. Hogan explicitly declared that he had reviewed the Specification and Claims of the present Application. See outstanding OA at page 4, second paragraph. In the Specification, attachment points 523, 525 are described *inter alia* at page 32, lines 12-18 and are clearly depicted in the drawings, including Figs. 5A and 5C. Fig. 5A depicts an example in which discrete sample nodes 529 are attached at attachment point 523 to structural array 520A that maintains sample structures 522, 524 in a predetermined spatial relationship using radial elements 521. See also page 32 at lines 1-18. Having read the Specification and Claims, a skilled artisan such as Mr. Hogan could have reasonably been expected to understand the teachings of the

Specification and appreciated the scope of the Claims. Therefore, the Examiner erred in dismissing a declaration made by a co-inventor of cited prior art.

Conclusion

For the foregoing reasons, Appellants respectfully request that all the pending claims be deemed allowable by this honorable Board.

Date: June 13, 2006

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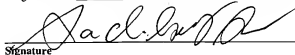


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CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10*

(When using Express Mail, the Express Mail label number is *mandatory*; Express Mail certification is *optional*.)

I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service "Express Mail Post Office to Addressee", Mailing Label No. EV 632470850 US, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Signature

Date: June 13, 2006

(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

VII. Claims Appendix

1. A sample carrier comprising:
a structural array; and
a plurality of discrete sample nodes; each of said plurality of discrete sample nodes being removably attached to said structural array at a respective attachment point and comprising a sample support medium operative to carry a discrete sample in desiccated form.
2. The sample carrier of claim 1 wherein each of said plurality of discrete sample nodes is operative to carry a biological sample.
3. The sample carrier of claim 2 wherein said biological sample is a protein.
4. The sample carrier of claim 2 wherein said biological sample is a polynucleotide.
5. The sample carrier of claim 4 wherein said polynucleotide is DNA.
6. The sample carrier of claim 1 wherein each of said plurality of discrete sample nodes is operative to carry a non-biological sample.
7. The sample carrier of claim 1 further comprising identifying indicia.
8. The sample carrier of claim 7 wherein said indicia are decipherable by an optical sensor.
9. The sample carrier of claim 1 wherein each of said plurality of discrete sample nodes comprises an associated transceiver operative to transmit a unique signal.
10. The sample carrier of claim 9 wherein said transceiver is further operative to receive a control signal from a remote device.
11. The sample carrier of claim 1 wherein each of said plurality of discrete sample nodes is solid.
12. The sample carrier of claim 1 wherein each of said plurality of discrete sample nodes is porous.

13. The sample carrier of claim 1 wherein each of said plurality of discrete sample nodes is constructed of said sample support medium.
14. The sample carrier of claim 13 wherein said sample support medium comprises cellulose.
15. The sample carrier of claim 13 wherein said sample support medium comprises a polymer.
16. The sample carrier of claim 15 wherein said polymer is polystyrene.
17. The sample carrier of claim 13 wherein said sample support medium is derivatized.
18. The sample carrier of claim 17 wherein said sample support medium is positively charged.
19. The sample carrier of claim 17 wherein said sample support medium is negatively charged.
20. A sample carrier comprising:
 - a plurality of structural arrays supported in a predetermined spatial relationship;
 - and
 - a plurality of discrete sample nodes; wherein each of said plurality of discrete sample nodes is removably attached to one of said plurality of structural arrays at a respective attachment point and comprises a sample support medium operative to carry a discrete sample in desiccated form.
21. The sample carrier of claim 20 wherein each of said plurality of structural arrays is supported in a predetermined spatial relationship relative to a respective sample container.
22. The sample carrier of claim 20 wherein each of said plurality of structural arrays is supported in a predetermined spatial relationship relative to a respective well of a multi-well plate.
23. The sample carrier of claim 20 wherein each of said plurality of discrete sample nodes is operative to carry a biological sample.

24. The sample carrier of claim 23 wherein said biological sample is a protein.
25. The sample carrier of claim 23 wherein said biological sample is a polynucleotide.
26. The sample carrier of claim 25 wherein said polynucleotide is DNA.
27. The sample carrier of claim 20 wherein each of said plurality of discrete sample nodes is operative to carry a non-biological sample.
28. The sample carrier of claim 20 further comprising identifying indicia.
29. The sample carrier of claim 28 wherein said indicia are decipherable by an optical sensor.
30. The sample carrier of claim 20 wherein each of said plurality of discrete sample nodes comprises an associated transceiver operative to transmit a unique signal.
31. The sample carrier of claim 30 wherein said transceiver is further operative to receive a control signal from a remote device.
32. The sample carrier of claim 20 wherein each of said plurality of discrete sample nodes is solid.
33. The sample carrier of claim 20 wherein each of said plurality of discrete sample nodes is porous.
34. The sample carrier of claim 20 wherein each of said plurality of discrete sample nodes is constructed of said sample support medium.
35. The sample carrier of claim 34 wherein said sample support medium comprises cellulose.
36. The sample carrier of claim 34 wherein said sample support medium comprises a polymer.
37. The sample carrier of claim 36 wherein said polymer is polystyrene.
38. The sample carrier of claim 34 wherein said sample support medium is derivatized.

39. The sample carrier of claim 38 wherein said sample support medium is positively charged.

40. The sample carrier of claim 38 wherein said sample support medium is negatively charged.

41. (Withdrawn) A method of transferring a specimen to a sample carrier; said method comprising:

providing a sample carrier comprising a structural array supporting a plurality of discrete sample nodes; each of said plurality of discrete sample nodes comprising a sample support medium operative to support a sample of said specimen in desiccated form; and

contacting said plurality of discrete sample nodes to said specimen.

42. (Withdrawn) The method of claim 41 wherein said specimen is a solid.

43. (Withdrawn) The method of claim 41 wherein said specimen is gaseous.

44. (Withdrawn) The method of claim 41 wherein said specimen is a liquid.

45. (Withdrawn) The method of claim 41 further comprising selectively applying a preservative to said plurality of discrete sample nodes subsequent to said contacting.

46. (Withdrawn) The method of claim 45 wherein said preservative is operative to desiccate said specimen transferred to said plurality of discrete sample nodes.

47. (Withdrawn) The method of claim 41 further comprising washing said plurality of discrete sample nodes subsequent to said contacting.

48. (Withdrawn) The method of claim 41 further comprising allowing said plurality of discrete sample nodes to desiccate subsequent to said contacting.

49. (Withdrawn) A method of transferring specimens to a sample carrier; said method comprising:

providing a sample carrier comprising a plurality of structural arrays, each of said plurality of structural arrays being supported in a predetermined spatial relationship relative to a respective specimen container and supporting a plurality of discrete sample nodes; each of said plurality of discrete sample nodes comprising a sample support medium operative to support a sample of a respective specimen in desiccated form; and

contacting said plurality of discrete sample nodes supported by selected ones of said plurality of structural arrays to said respective specimen.

50. (Withdrawn) The method of claim 49 wherein said contacting comprises bringing said plurality of discrete sample nodes supported by each of said plurality of structural arrays into contact with a specimen in said respective specimen container.

51. (Withdrawn) The method of claim 49 wherein said respective specimen is a solid.

52. (Withdrawn) The method of claim 49 wherein said respective specimen is gaseous.

53. (Withdrawn) The method of claim 49 wherein said respective specimen is a liquid.

54. (Withdrawn) The method of claim 49 further comprising applying a preservative to said plurality of discrete sample nodes supported by selected ones of said plurality of structural arrays subsequent to said contacting.

55. (Withdrawn) The method of claim 54 wherein said preservative is operative to desiccate said respective specimen transferred to said plurality of discrete sample nodes.

56. (Withdrawn) The method of claim 49 further comprising washing said plurality of discrete sample nodes subsequent to said contacting.

57. (Withdrawn) The method of claim 49 further comprising allowing said plurality of discrete sample nodes to desiccate subsequent to said contacting.

58. A sample carrier comprising:

a structural array comprising a plurality of discrete sample nodes; wherein each of said plurality of discrete sample nodes is removably attached to said structural array at a respective attachment point and comprises a discrete sample support medium operative to support sample material in desiccated form; and

a specimen carried by said sample support medium in desiccated form at one or more of said plurality of discrete sample nodes.

- 59. The sample carrier of claim 58 wherein said specimen is biological.
- 60. The sample carrier of claim 59 wherein said specimen is a protein.
- 61. The sample carrier of claim 59 wherein said specimen is a polynucleotide.
- 62. The sample carrier of claim 61 wherein said polynucleotide is DNA.
- 63. The sample carrier of claim 58 wherein said specimen is non-biological.
- 64. The sample carrier of claim 58 wherein said sample support medium is solid.
- 65. The sample carrier of claim 58 wherein sample support medium is porous.
- 66. The sample carrier of claim 58 wherein said sample support medium comprises cellulose.
- 67. The sample carrier of claim 58 wherein said sample support medium comprises a polymer.
- 68. The sample carrier of claim 58 wherein said sample support medium is derivatized.
- 69. The sample carrier of claim 58 wherein said sample support medium is treated with a chemical compound.

IX. Evidence Appendix

None.

None.

X. Related Proceedings Appendix